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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/921,429 | 08/02/2001 | Lars Morch Groth | NN-6200.200 US | 3993 |

23650 7590 07/29/2004

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| EXAMINER |
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PICKETT, JOHN G

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| ART UNIT | PAPER NUMBER |
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3728

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,429

Applicant(s)

GROTH, LARS MORCH

Examiner

Gregory Pickett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office action acknowledges the applicant's Amendment submitted 20 April 2004. Claims 19-22 are pending in the application.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. In light of the applicant's amendment, the objection to the specification is hereby withdrawn.

Claim Rejections - 35 USC § 112

4. In light of the applicant's amendment, the rejection of claims 19 and 20 under 35 U.S.C. 112, second paragraph is hereby withdrawn.

Claim Rejections - 35 USC § 103

5. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,873,462) in view of Current (US 4,203,518).

Regarding claims 19 and 20, Nguyen et al discloses a tool (10) with a cylinder-shaped base member (30) having a bottom surface (bottom of 30), an upper surface (32), a cylindrical wall surface (outside wall of 30), and spaced cavities (31) containing needle assemblies (100) and having a sterility barrier (150); a cover (20) having a first

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part (top surface of 20) and a slot (21). The tool of Nguyen provides a means for preventing one directional rotation of the cover in the form of ratchet assemblies (33 and 25) and provides a means for preventing the cover from rotating more than 360 degrees in the form of first protrusion (26) on cover (20) and second protrusion (36) on base member (30). The tool of Nguyen provides a means for preventing rotation (44) of the pen needle while the needle is in the cavity (31). Nguyen et al meets all limitations claimed by the applicant except:

Nguyen et al does not disclose radial extending cavities or a cover with a cylindrical wall.

Current discloses a cover (24) with a second part (28) parallel to a cylindrical wall (20) and a slot (34) provided on the second part (28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tool of Nguyen et al by rotating the vertical compartments to the horizontal position and providing the magazine with radial extending cavities and a cover as taught by Current in order to reduce the overall height of the container. Such a modification is deemed a mere rearrangement of parts, and it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

With the overall purpose of modification being height reduction, it would have been obvious to one of ordinary skill in the art to limit the height as much as possible. As such, it would have been obvious to limit the magazine height of Nguyen-Current to the width of the cavities (Nguyen et al, Figure 6); thereby creating a total magazine

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height that is insubstantially greater than the diameter of the needle assembly. The tool of Nguyen-Current is capable of functioning as claimed by the applicant.

Regarding claim 21, the tool of Nguyen-Current, as applied to claim 19 above, provides the claimed tool structure. Nguyen teaches the step of removal of the sterility barrier (Col. 5, lines 30-32). Nguyen teaches the manual application of the needle assembly onto the injection device and therefore inherently discloses the grasping of the tools in the users hands. Nguyen anticipates a screw connection (Col. 5, lines 36-38) and therefore the rotation of the injection device and tool for connection. The specific degree of rotation required would depend on the depth of the thread engagement and is deemed an obvious matter of design choice.

Regarding claim 22, the tool of Nguyen-Current, as applied to claim 19 above, discloses the claimed invention.

Response to Arguments

6. Applicant's arguments filed 20 April 2004 have been fully considered but they are not persuasive.

7. In response to the applicant's arguments that the radial storage of the needles is one of the least efficient, thereby indicating that the references teach away from the claimed invention, the applicant bases the analysis on a volumetric comparison to a rectangular configuration. The rectangular configuration is not relevant to the comparison since such an arrangement does not consider the secondary functions of

Nguyen et al and would destroy the reference. What must be considered is the optimal reduction in size of the Nguyen et al reference while maintaining the necessary features of the invention. As the EPO opinion was not included with this amendment, a full evaluation of their position is not possible. However, the examiner does not see where the external diameter would need to be increased in order to rotate the needles of Nguyen et al in a radial direction as taught by Current. The needles have a smaller end then at the connection point, which lends itself to such an arrangement. At most, the internal diameter of openings 22 and 37 would need to be slightly reduced. But since this would in no way change the function of the arrangement, it would be a mere change in size. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Therefore, with the external diameter constant, the only way to reduce overall volume of the Nguyen et al device is height reduction ($V=h*\pi*(d/2)^2$), which is the motivation presented by the examiner in the previous Office actions. While this arrangement may not be the overall optimum in compact storage, one of ordinary skill in the art would recognize it as an improvement on the overall size of Nguyen et al while maintaining the functionality of Nguyen et al.

8. In response to applicant's argument that none of the references teaches a tool with increased leverage, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pickett whose telephone number is 703-305-8321. The examiner can normally be reached on Mon-Fri, 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gregory Pickett
Examiner
26 July 2004



Mickey Yu
Supervisory Patent Examiner
Group 3700